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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Walter Schubert

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EXAMINER

BASS, DIRK R

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

11/02/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/686,865	Applicant(s) SCHUBERT, WALTER	
	Examiner DIRK BASS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>May 7, 2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants response filed March 19, 2009 is acknowledged. Claims 11-20 are withdrawn from consideration. Claims 1-10 and 21 are pending and further considered on the merits. Upon further consideration of the claims, the examiner incorporates a species election as seen in this office action.

Election/Restrictions

2. Claim 6 is generic to the following disclosed patentably distinct species: the species recited in claim 7, and the species recited in claim 8. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly

and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

3. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. During a telephone conversation with Lou Isaf on October 23, 2009 a provisional election was made without traverse to prosecute the invention of the species recited in claim 7. Affirmation of this election must be made by applicant in replying to this Office action. Claim 8 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1-3, 5-7, 10, and 21** are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Blumenfield et al., US 6300124 (Blumenfield, IDS).

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Regarding claims 1-3 and 21, Blumenfield discloses a method for preparing biological samples (see "histochemical section", col. 14, l. 17-30) for analysis comprising:

- a. Placing the biological sample on a two-dimensional support (col. 14, l. 17-18 and col. 20, l. 60-62);
- b. Air drying the biological sample (col. 14, l. 17-20 and col. 20, l. 60-62);
- c. Applying protein-precipitating or denaturing first solution L1 to the biological sample on the support (see "PCR buffer containing the missing reagents", col. 21, l. 1-4 and "PCR reagent mixture lacks at least one reagent, such as enzyme", col. 20, l. 65-66) at a first temperature T1 (inherently disclosed) for a first time period Z1 (inherently disclosed);
- d. Applying a protein-precipitating or denaturing solution L2 to the biological sample on the support (see "100% ethanol", col. 21, l. 15-17) at a second temperature T2 for a predetermined second time period Z2 on the support, with T2 being lower than T1 (inherently disclosed) and Z2 being longer, equal to, or shorter than Z1 (inherently disclosed); and
- e. Drying the sample on the support (see "slides are air dried", col. 21, l. 15-16).

Blumenfield further discloses a method wherein said biological sample is a cell or tissue sample (see "histochemical section", col. 14, l. 17-30) (Claim 5), said solution L2 is an organic solvent (see "100% Ethanol", col. 21, l. 15-17) (Claims 6-7), and after performing the method steps defined above, subjecting said biological samples to a nucleic acid determination method (col. 21, l. 21-58) (Claim 10).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. **Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over Blumenfield et al. in view of Cech et al., USPA 2003/0096344 (Cech).

Regarding claim 4, Blumenfield fails to explicitly disclose a method wherein a biological sample is frozen.

Cech teaches that it is desirable to freeze a biological sample for later analysis (§ 0363).

At the time of invention, it would have been obvious to one skilled in the art to add the freezing step of Cech with the method of Blumenfield in order to preserve or save the biological sample for later use.

9. **Claim 9** is rejected under 35 U.S.C. 103(a) as being unpatentable over Blumenfield et al.

Regarding claim 9, Blumenfield discloses a method wherein T1 is about 80°C (col. 21, l. 1).

While Blumenfield fails to explicitly disclose a method where the temperature is within the claimed range, it would have been obvious to one skilled in the art at the time the invention was made to have T1 fall within the claimed range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (MPEP 2144.05, Section II, Part A).

Response to Arguments

10. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIRK BASS whose telephone number is (571) 270-7370. The examiner can normally be reached on Mon - Fri (9am-4pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

10/28/2009

/Yelena G. Gakh/
Primary Examiner, Art Unit 1797

/DRB/
Dirk R. Bass